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Re-evaluation Note REV2015-10

Special Review of Paraquat: Proposed Decision for Consultation

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1.0 Introduction

Pursuant to subsection 17(2) of the *Pest Control Products Act*, the Pest Management Regulatory Agency (PMRA) initiated a special review of pest control products containing paraquat based on a prohibition by the European Union (EU) in 2007 for health and environmental reasons. The prohibition arose as a result of a decision by the EU Court of First Instance (Court of First Instance 2007) to annul the Directive 2003/112/EC (European Commission, 2003a) authorizing the inclusion of paraquat as a plant protection product in the EU. The relevant aspects of the Court decision for the purposes of subsection 17(2) are those that overturned the European Commission decision based on risks to human health and the environment. In addition, a previous decision by Sweden in 1983 (Rotterdam Convention, 2006), to prohibit the use of paraquat as a pesticide, was also considered in this special review. The initiation of the special review of paraquat was announced in Re-evaluation Note REV2013-06, *Special Review Initiation of 23 Active Ingredients* (Canada, 2013).

As required by subsection 18(4) of the *Pest Control Products Act*, the PMRA has evaluated the aspects of concern that prompted the special review of paraquat. The aspects of concern are relevant to human health and the environment, and were identified as:

1) Potential risk of health effects as a result of accidental exposure in occupational settings
2) Potential risk to workers mixing, loading and applying paraquat using backpack equipment
3) Persistence in soil and sediment
4) Potential effects to sediment dwelling organisms
5) Potential reproductive risk to birds and potential risk to mammals

2.0 Uses of Paraquat in Canada

Paraquat, a contact non-selective herbicide, is registered in Canada for the control of grasses and broadleaf weeds in established crops (for example fruit crops, filbert and hazelnuts, and vegetables) or as a pre-emergent treatment (for example potatoes and field crops) at the maximum application rate of 1.1 kg paraquat as dichloride/hectare. Paraquat can be applied alone or tank-mixed with other herbicides using groundboom equipment and backpack sprayer. Appendix I lists all paraquat products that are currently registered under the authority of the *Pest Control Products Act*, and they are considered in this special review.

In Canada, a re-evaluation of paraquat was completed in 2006. The re-evaluation included an assessment of the risks to human health and the environment, and, paraquat was found acceptable for continued registration with the revised conditions of use (Canada, 2004; Canada, 2006). Subsequently in 2009, additional risk reduction measures were implemented to further minimize occupational exposure (Canada, 2009).

3.0 Aspect of the Pest Control Product that Prompted the Special Review

In the EU, the use of paraquat as a plant protection product was prohibited in 2007 as a result of the EU's Court of First Instance decision (Court of First Instance, 2007) to annul the Directive 2003/112/EC, authorizing the inclusion of paraquat in the list of active substances authorised for incorporation in plant protection products in the EU. The findings of the Court of First Instance related to failing to protect human health and the environment were considered as part of this special review of paraquat. The concerns identified were:

- The potential risk to workers mixing, loading and applying paraquat using backpack equipment.
- The potential reproductive risk to birds and potential risk to mammals.

In Sweden, as outlined in the PIC Circular XXIII (Rotterdam Convention, 2006), the use of paraquat was banned in 1983 due to health and environmental concerns. Sweden reported that paraquat was a highly toxic substance and accidental exposure to this active ingredient may result in serious health effects, including death. The PIC Circular indicated health concerns related to *"its acute high toxicity, risk for irreversible effects on health and for accidents during handling and the use of the substance"*. The lack of an effective antidote was also reported (UNEP, 2008; UNEP, 2009b). With regards to environmental concerns, (Rotterdam Convention, 2006), Sweden reported that paraquat is highly persistent in soil and sediment and is expected to accumulate in the soil after repeated exposure. While *"possible effect on sediment dwelling organisms"* was cited in the PIC Circular XXIII (Rotterdam Convention, 2006), no further information regarding the effects or risk to sediment dwelling organisms was included in the PIC Circular or, identified in the available information from Sweden (UNEP, 2008; UNEP, 2009 a, b; UNEP, 2010). The expected effect of the regulatory action was identified in the PIC Circular XXIII (Rotterdam Convention, 2006) as "*risk reduction in the agriculture sector*". Based on the review of the information from Sweden, the PMRA has identified the following aspects of concern:

- Potential risk of health effects as a result of accidental exposure in occupational settings
- Persistence in soil and sediment
- Potential effects to sediment dwelling organisms

4.0 PMRA Evaluation of the Aspect of the Pest Control Product that Prompted the Special Review

Following the initiation of the special review of paraquat, the PMRA requested information from provinces and other relevant federal departments and agencies, in accordance with subsection 18(2) of the *Pest Control Products Act*. No information related to the aspects of concern was received.

To evaluate the aspects of concern related to human health and the environment, the PMRA has considered currently available relevant scientific information, which includes information considered for the re-evaluation of paraquat (Canada, 2004; Canada, 2006), and any relevant information obtained since then [for example, information on Canadian and the American incident reports, and information from United States Environmental Protection Agency (USEPA), and the EU and Sweden].

4.1 Potential risk of health effects as a result of accidental exposure in occupational settings

The potential risk of health effects from accidental exposure in occupational setting was assessed taking into consideration the toxicity profile of paraquat, information from incident reports on paraquat submitted through the Health Canada Pesticide Incident Reporting Program (IRP), information from other jurisdictions (for example Canadian Poison Control Centers, USEPA and the California Department of Pesticide Regulation database) and the existing conditions of use.

Paraquat is highly acutely toxic via dermal, inhalation and oral routes of exposure and is a severe dermal and eye irritant but not a skin sensitizer (Canada, 2004; USEPA, 1997; USEPA, 2014). The end-use product, Gramoxone Liquid Herbicide is also highly toxic via the inhalation route, severely toxic via the dermal route of exposure, and it is severely irritating to skin and eyes.

Incident reports submitted to the PMRA (as of August 2015) that had a high degree of association with paraquat and were related to the aspect of concern were considered in this special review. This includes 22 incidents (10 occurred in Canada and the remaining in the United States), and included dermal and/or inhalation exposures from mixing/loading and spraying operations, spill, or leakage, as well as accidental ingestion of paraquat. Reported effects were of serious nature in most cases, including permanent skin damage, oral and esophageal ulcerations, and 2nd and 3rd degree chemical burns. Minor to moderate eye irritations were also reported. Accidental ingestion resulted in life threatening or fatal outcomes. In almost all cases of accidental ingestion, the product was ingested after being put into a beverage container despite the warning on the current end-use product label to never transfer the product to another container; two cases were unknown. Two respiratory incidents occurred while spraying the product and included minor to severe respiratory effects (for example shortness of breath, tachypnea, and pleural effusion).

The review of incident reports related to human health identified the following main health hazards:

1) Corrosive nature of paraquat resulting in severe skin and eye effects, and
2) Accidental ingestion of paraquat from unmarked containers resulting in life-threatening or fatal outcomes.

In the serious incidents involving dermal exposure, there was a delay between exposure to paraquat and the onset of symptoms. Significant dermal absorption in the reported cases was considered likely from compromised skin integrity (for example due to dermatitis or skin lesions from paraquat exposure), and, systemic poisoning through dermal route has been reported in the

scientific literature (Smith, 1998; Zhou et al, 2013). It should be noted that the current product label includes a warning statement indicating that, although intact skin is an effective barrier to paraquat, contact with irritated or cut skin or repeated contact with intact skin may result in poisoning.

As with dermal exposure, the severe ocular effects develop gradually, reaching maximum intensity up to 24 hours following exposure. Paraquat is corrosive to the eye and can result in conjunctival or corneal injury and mild iritis. Some injuries may be reversible, but patients may be left with residual corneal scarring sufficient to cause corneal opacities and blindness.

Currently, the Gramoxone Liquid Herbicide label includes several precautionary label warnings and requires workers to use personal protective equipment to minimize dermal and ocular exposure. For example, the label includes hazard label statements "*Skin Irritant and Corrosive to Eyes*" and "*Harmful if absorbed through skin*" and "*DO NOT get on skin or clothing*". Mixers/loaders are instructed to wear a long-sleeved shirt, long pants, shoes with socks, chemical resistant gloves, and a chemical resistant apron. Workers using backpack sprayers are also instructed to wear coveralls over a long-sleeved shirt and long pants. The label also directs the user to remove contaminated clothing as soon as possible. Furthermore, the label requires applicators, mixers/loaders and other users to wear protective eyewear (such as goggles and/or face shield) and recommends a consultation with an eye specialist after eye splashes. However, based on the review of the submitted incident reports, additional risk reduction measures (for example additional personal protective equipment (PPE), additional warning statements and treatment advice) are proposed to further minimize the potential for dermal exposure (see Section 5.0).

With respect to the concern for accidental ingestion of paraquat in occupational settings, the PMRA determined that despite the addition of a dye and a stenching agent to the product and, the current label direction to *"Never transfer to other containers"* and a label warning statement *"Fatal if swallowed"*, cases of accidental ingestion occurred in Canada and the United States. In almost all cases reported, the paraquat product was ingested after being transferred to an unmarked container. The details provided in some cases suggest that the product was transferred to a different container to combine with tank-mix partners or to store the product. In all of the scenarios, beverage containers (for example pop bottles, water bottles) would be seen as convenient options to measure, transport, and/or store paraquat. Although, the current product labels instruct never to transfer the product to other containers, the available information indicates that the dangerous practice of transferring the product to beverage or smaller containers continues. Therefore, additional risk reduction measures are proposed to minimize the potential for accidental ingestion of paraquat (see Section 5.0).

To minimize inhalation exposure, the PMRA had previously implemented several mitigation measures (for example requirement of a respirator for workers during mixing, loading, and application activities and a label warning statement "*Fatal if inhaled*"). However, additional label clarification related to the use of a respirator is proposed to further reduce the potential for inhalation exposure (see Section 5.0).

4.2 Potential risk to workers mixing, loading and applying paraquat using backpack equipment

According to the current use pattern, the Gramoxone product can be applied using backpack equipment and the routes of exposure include both dermal and inhalation routes. To assess the potential risk to workers mixing, loading and applying paraquat using a backpack sprayer, the PMRA considered the registered use pattern, the toxicological profile of paraquat and its associated end-use product, information from incident reports and risk reduction measures proposed to minimize accidental exposure under occupational setting, the available surrogate exposure data, as well as information from the USEPA pertaining to dermal absorption.

As indicated in Section 4.1, to minimize the potential for dermal exposure to paraquat, additional PPE consisting of chemical-resistant coveralls over a long-sleeved shirt and long pants, socks and chemical resistant boots, and chemical-resistant gloves for all workers mixing/loading and applying paraquat using backpack equipment is proposed (see Section 5.0). The use of a respirator to minimize the potential for inhalation exposure is currently required on the end-use product label for workers using backpack equipment.

Taking into consideration the toxicity profile of paraquat indicating potential greater sensitivity of humans to paraquat than animals and the corrosive nature of paraquat resulting in skin damage leading to a greater absorption of paraquat via the dermal route, the PMRA concluded that the available animal data may not adequately characterise the potential human health toxicity. However, since the level of daily exposure for workers is expected to be minimal with the proposed PPE above, the risk for workers applying paraquat using backpack equipment is not expected to be a concern. To further clarify use instructions related to the use of backpack sprayers and respirators, the PMRA is proposing additional label updates (Section 5.0).

4.3 Persistence in soil and sediment

Paraquat is soluble in water (water solubility of 620 g/L at 20°C), is not expected to volatilize from moist soils and water surfaces (vapour pressure of less than 1×10^{-2} mPa at 25°C) and is not expected to bioaccumulate based on the log K_{ow} of -4.5 (Canada, 2004).

Paraquat does not hydrolyze and its photodegradation in aqueous solutions is very slow. Paraquat is stable to biotransformation in soil. It is immobile in soil (silty clay loam, loam, loamy sand and sand). Based on short and long term field dissipation studies, paraquat is expected to be persistent and to accumulate slightly with repeated application. No half-lives were calculated in the available field studies. However, a possible half-life of more than 10 years was reported (USEPA, 1997).

Paraquat is likely to enter surface waters systems, transported primarily through soil particles. It is expected to be bound to benthic or suspended sediments and probably to plant material in the water, thus reducing its bioavailability to aquatic animals. In the soil:water system, paraquat was removed from the water column with a half-life of less than 2 weeks and was reported to degrade to undetectable levels in 35 weeks without sediment or plants, in 6-8 weeks with sediment present, and in 3-4 weeks with sediment and aquatic plants present (USEPA, 1997; USEPA,

2002). A recommended best practice to reduce the potential runoff of paraquat is currently included on the end use product label. However, these will be updated to meet the current labelling standard (see Section 5.0).

4.4 Potential effects to sediment dwelling organisms

The potential risk to sediment dwelling organisms was assessed based on the available information from the EU (European Commission, 2000; European Commission, 2003). Paraquat applied to sediment (at 100 mg paraquat ion per kg) and to water (at 0.367 mg paraquat ion/L) had no effect on the survival or development of *Chironomus riparius*. Consequently, a 21-day No Observed Effect Concentration (NOEC) in sediment of 100 mg paraquat ion/kg and a 21-day water only NOEC of 0.367 mg paraquat ion./L were established for *Chironomus sps.*

Based on the highest application rate of paraquat in Canada, the risk to sediment dwelling organisms is not expected to be of concern. Furthermore, to minimize exposure from spray drift to aquatic system, buffer zones were established by the PMRA based on a more conservative end point (NOEC=0.22 µg a.i/L for fresh water diatom) than the NOEC values reported for *Chironomus sps.*

4.5 Potential reproductive risk to birds and potential risk for mammals

Risks to birds and mammals, expressed as risk quotient (RQ), were calculated by dividing the estimated environmental concentrations (EECs) by the most sensitive toxicity endpoint. The estimated risk quotients were then compared to the level of concern (LOC). For acute and chronic exposures to birds and mammals, the LOC is 1.0.

The estimated environmental concentrations (EECs) on potential food items (for example vegetation, seeds and grains) were calculated assuming a direct application at the maximum seasonal application rate of 0.8 kg ion/ha (equivalent to 1.1 kg paraquat as dichloride/ha). The estimated daily exposure (EDE) were calculated for birds and mammals, taking into consideration specialized feeding guilds (herbivores, frugivores, insectivores, and granivore). Also, it was assumed that the diet is comprised entirely of a particular dietary item.

Potential reproductive risk to birds: For characterization of reproductive risks to birds, a NOEL of 1.7 mg ion/kg bw/day was selected from the reproduction study in the Mallard duck based on the reduction in the percentage of viable eggs, eggs set, normality of hatching, and number of 14-day old survival (USEPA, 1997; European Commission, 2003b).

The estimated chronic RQs exceed the level of concern for all sizes of birds both on- and off-field based on maximum and mean residues of paraquat following a broadcast spray application. However, based on the current use pattern (for example pre-emergent and post-cutting application to field crops; applications to established crops with lowboom sprayers fitted with drift-reducing shrouds or shields to minimize residue deposition on foliage, spot treatment), fields exposed to paraquat are not expected to be a significant food source for birds. Furthermore, environmental fate data indicate strong adsorption to biological materials leading to paraquat becoming less bioavailable. Based on the above, the chronic risk to birds resulting from

paraquat applications under the current conditions of use is not expected to be of concern. However, based on the potential reproductive effects of paraquat on birds, a hazard label statement "*Toxic to birds*" is proposed to be added to the Gramoxone Liquid Herbicide label (see Section 5.0).

Potential risks to mammals: The available mammalian toxicology data indicate that paraquat is moderately to highly toxic to small mammals based on acute oral toxicity with LD_{50} ranging 91to 250 mg ion/kg-bw in the rat (USEPA, 1997; USEPA, 2011; USEPA, 2014). Also, the residues of paraquat measured in vegetation, coupled with evidence of pulmonary and lingual lesions, demonstrate the sensitivity of the hare to paraquat (USEPA, 1997). No effects related to survival, growth and reproduction were reported in a 3-generation reproduction study in the rat (USEPA, 2011).

For characterization of acute and chronic (reproductive) risks to mammals, a rat LD_{50} of 91 mg ion/kg and the NOEL of 7.5 mg ion/kg (highest dose tested in a 3-generation reproduction study) were selected.

The level of concern for mammals is exceeded based on the acute and chronic basis. However, as for birds, fields treated with paraquat are not expected to be a significant food source for mammals, based on the use pattern and the available environmental fate data. Consequently, it was concluded that the potential risk to mammals under the current conditions of use will be lower than the estimated risk. However, based on the acute toxicity to mammals, a hazard label statement *"Toxic to small wild mammals"* is proposed on Gramoxone Liquid Herbicide label (see Section 5.0).

Information submitted to the PMRA through the Canadian incident reporting database, was also reviewed for purposes of the special review of paraquat. As of August 2015, no additional information related to the environmental aspects of concern was identified.

5.0 Proposed Risk Mitigation Measures

Based on the analysis of the aspects of concern, the PMRA is proposing the following additional risk reduction measures to further reduce the potential risk to human health and the environment:

1) Designation of the end-use product as 'Restricted Class' based on the toxicity profile of paraquat and the potential for accidental exposure. The end use product is proposed to be used by individuals holding an appropriate pesticide applicator certificate or license recognised by the provincial/territorial pesticide regulatory agency, where the pesticide application is to occur.
2) Additional PPE consisting of chemical-resistant coveralls over a long-sleeved shirt and long pants, socks and chemical resistant footwear, chemical-resistant gloves, protective eyewear for workers during mixing, loading, application, clean-up and repair. A respirator for mixer/loaders, as well as for applicators (unless enclosed cab groundboom equipment is used).

3) Additional hazard warnings regarding acute oral, dermal, and eye hazard, toxicological information related to the seriousness of health effects, and revised first aid and treatment advice.
4) Reducing the concentration of paraquat in the end-use product to lower the potential for accidental ingestion of a lethal dose of paraquat.
5) Modified packaging to include a built in capacity for measuring the required amount of the product.
6) Prohibition of tank mixing with other pest control products.
7) Development of a stewardship/outreach program for applicators and vendors.

Furthermore, based on the review of the current Gramoxone Liquid Herbicide label, the PMRA is proposing additional label updates related to the use directions for backpack (indicating the use of backpack sprayer for spot treatment for filbert and hazelnuts) and groundboom (specifying lowboom sprayers for field crops) equipment, respirator and re-entry instructions. In addition, standard environmental hazard label statements related to the toxicity to birds and mammals, as well updates to runoff label statements are proposed.

The proposed timeline for implementation of label amendments is 1 April 2016 and the proposed timeline for reducing the concentration of paraquat in the end-use product and packaging modifications is 1 April 2017.

6.0 Proposed Special Review Decision for Paraquat

Evaluation of available scientific information related to the aspects of concern for human health and the environment, indicated that the registered products containing paraquat are acceptable for continued registration taking into account the proposed revised conditions of use. On this basis, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act*, is proposing to amend the current registration of products containing paraquat for sale and use in Canada with the proposed risk mitigation measures and implementation timelines described under Section 5.0.

This proposed special review decision is a consultation document.[1] The PMRA will accept written comments on this proposal up to 30 days from the date of publication of this document. Please forward all comments to Publications (please see contact information on the cover page of this document).

7.0 Next Steps

Before making a special review decision on paraquat, the PMRA will consider all comments received from the public in response to this consultation document. A science-based approach will be applied in making a final decision on paraquat. The PMRA will then publish a special review decision document, which will include the decision, the reasons for it, a summary of the comments received on the proposed decision and the PMRA's response to these comments.

[1] "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

Appendix I Registered Products Containing Paraquat as of 14 August 2015

Registration Number	Marketing Class	Registrant	Product Name	Formulation	Guarantee
21247	Technical	Syngenta Canada Inc.	Paraquat Technical	Solution	32%
21273	Manufacturing Concentrate	Syngenta Canada Inc.	Paraquat Dichloride Manufacturing Concentrate	Solution	32%
8661	Commercial	Syngenta Canada Inc.	Gramoxone Liquid Herbicide With Wetting Agent	Solution	200g/L

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